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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/522,828

01/31/2005

Ulrich Beutler

PD/4-33305A

6586

1095

7590

05/14/2008

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER

MANOHARAN, VIRGINIA

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

05/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/522,828	Applicant(s) BEUTLER ET AL.	
	Examiner Virginia Manoharan	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/31/05 & 05/09/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors, e.g., typographical, grammar, idiomatic, syntax and etc. Applicants' cooperations are requested in correcting any errors of which applicants may become aware in the specification.

Claims 1-10 are rejected under 35 U.S.C. 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and fails to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a). The temperature and pressure parameters appear to be important to applicants' invention, but were not recited in the independent claim. Note e.g., page 4, first full paragraph of the specification.

b). The specification recites e.g., "Terbinafine base" at page 4, line 4, as opposed to the claimed "terbinafine in free base. The former would presupposed a terbinafine in base or non-free base form.

c). The claimed "above 100⁰ C" in claim 3 would read e.g., on 150, 450, and etc., degrees centigrades which are not contemplated in the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a). The inconsistent used of terminology in the claims is improper. For examples: “the resultant product” in claim 1, as opposed to “the purified product” in claims 5 and 7 and the “resultant purified product” in claim 6.

b). The phrases “preferably at least” and “especially at least ”, (claim 7), fail to ascertain the claimed invention with precision.

c). Claim 9, as recited, is ambiguous with the recitation of “according to any one of claim 1”

d). There is insufficient antecedent basis for the limitation “acid addition salt form” recited in claim 1, line 3 as it is not initially recited in the base claim.

Claims 9 and 10 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The products recited in the claims can be made by many other ways than the method of claim 1, and therefore is an improper claim.

This is recognized by applicants noting e.g. ,the stipulation at 4, lines 1-3 of the specification, “ Example 13 ofBanyu EP 0 421302 A2 describing a preparation of terbinafine, the crude mixture (free base) obtained after reaction is subjected to purification by silica gel chromatography”.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9 and 10 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Applicants' admission or Nakagawa et al (5,436,354).

Obviously, either EP 24587 or Nakagawa obtains a purified terbinafine or a terbinafine in free base or acid addition salt form as claimed. See applicants' admission at page 1, lines 3-4, that "... Terbinafine, particularly in the form of the hydrochloride acid addition salt form, is known from e.g. EP 24587". See also col. 15, lines 40-41 of the Nakagawa reference. [See section 706.03 (e) of the MPEP].

[It is noteworthy that where a product by process claim is rejected over a prior art product that appears to be identical although produced by a different process, the burden is upon applicants to come forward with evidence establishing an unobvious difference between the two. In re Marosi , 218 USPQ 289 (Fed. Cir. 1983)].

Claims 1, 4, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakagawa et al (5,436,354) and Castaldi et al (6,515,181).

Example 13 at col. 15 and the "concentrated under reduced pressure" process in Example 18 of Nakagawa would at least be suggestive of the claimed process for the purification of terbinafine by distillation as broadly claimed in claim 1.

Castaldi discloses (abstract) used of copper salts as catalyst as claimed in claim 8. It would have been obvious to an artisan to combine the above references as they are both directed to processing the same compound (terbinafine).

Claims 2-3, and 5-7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Tarquini et al discloses a process for preparing terbinafine.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to V. Manoharan whose telephone number is (571) 272-1450.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Glenn Caldarola can be reached on (571) 272-1444.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Virginia Manoharan/
Primary Examiner, Art Unit 1797

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